



## Certificate of Need Task Force

August 11, 2005

## Recap of July 14, 2005 Task Force Meeting

Issue	Task Force Recommendation
Principles to Guide the CON Program	•Revise draft and bring back to Task Force for further discussion and action
Obstetric Services	•Maintain requirement for CON
Home Health Agency Services	•Eliminate requirement for CON
Burn Care Services	•Reconsider previous recommendation based on information from Johns Hopkins Hospital

## Hospice Services: Summary of Positions in Support of Alternative Regulatory Strategies

	Deregulate from CON Review	Maintain Existing CON Review
<b>Need</b>	<ul style="list-style-type: none"> <li>• CON requirement for hospice does not address residential hospice programs; inpatient hospices are only regulated if they exceed the capital threshold.</li> <li>• Hospice programs can expand capacity on an unregulated basis by adding staff. This largely eliminates potential for determining that new agencies are needed, biasing the regulatory process in favor of existing hospices.</li> <li>• Hospice utilization is limited by the number of people facing death. The addition of new hospice programs will not, in and of itself, drive an increase in hospice utilization. There is no danger of unnecessary utilization of hospice services.</li> </ul>	<ul style="list-style-type: none"> <li>• Some states have seen unregulated market entry (except for licensure and Medicare certification) leading to proliferation of agencies and destabilization of service delivery for some period of time.</li> <li>• Operation Restore Trust in 1997 found fraud in hospices enrolling nursing home patients and providing limited or no services. The worst of this fraudulent conduct was concentrated in states without CON.</li> <li>• The current threshold requirement (250 cases) serves to approve additional hospice programs when needed.</li> </ul>
<b>Access</b>	<ul style="list-style-type: none"> <li>• Removal of the requirement for CON review would potentially increase access to hospice services by eliminating a barrier to the development of more programs.</li> <li>• Enforcement of authorized service areas for hospices is difficult due to home-based nature of service delivery and reliance on self-reporting of data used in monitoring.</li> </ul>	<ul style="list-style-type: none"> <li>• No indication that Marylanders lack access to hospice care; all jurisdictions served by at least one hospice program.</li> <li>• Removal of CON and resulting increase in for-profit hospices might result in “cherry picking” and thus restrict access for costly patients or those who are uninsured.</li> <li>• Access may be restricted in remote and rural areas which would be less profitable.</li> </ul>

## Hospice Services: Summary of Positions in Support of Alternative Regulatory Strategies (continued)

<p><b>Cost</b></p>	<ul style="list-style-type: none"> <li>•The addition of hospice programs would stimulate competition and could promote cost efficiencies.</li> <li>• Larger for-profit providers could achieve economies of scale by providing services to more clients.</li> </ul>	<ul style="list-style-type: none"> <li>•Hospice is a fixed price service where increased competition will not affect price. 80% of hospice care is paid by Medicare.</li> <li>•The current short ALOS stay in hospice makes the provision of care expensive (highest charges in first and final days); increased competition might exacerbate this problem.</li> <li>•Adding more agencies would increase competition for scarce nursing and other staff resources as well as for volunteers.</li> <li>•Adding more agencies would increase competition for limited charity dollars.</li> </ul>
<p><b>Quality</b></p>	<ul style="list-style-type: none"> <li>•Most hospice programs are Medicare certified and meet JCAHO certification requirements; though this certification is voluntary, increased competition would encourage participation.</li> <li>•Quality oversight already done by OHCQ</li> </ul>	<ul style="list-style-type: none"> <li>•CON review provides an initial, threshold review to determine whether a prospective hospice provider has financial resources, clinical sophistication, to obtain Medicare certification once licensed, thereby preventing marginal providers from entering market.</li> <li>• With increased competition, providers would have to divert funds to marketing rather than patient care thus potentially diluting quality.</li> </ul>

## Ambulatory Surgery Services: Summary of Positions in Support of Alternative Regulatory Strategies

	Deregulate from CON Review	Maintain Existing CON Review
<b>Need</b>	<ul style="list-style-type: none"> <li>• Because one OR facilities do not require Certificate of Need approval, the “playing field” is uneven, in addressing the question of need for new FASFs.</li> <li>• The existing exclusion of one OR facilities from CON review in effect partially deregulates this sector, so a total deregulation would not have a significant impact.</li> <li>• Since Maryland has allowed the ambulatory surgery market to develop with limited oversight, eliminating remaining constraints would permit the market to more appropriately allocate resources</li> </ul>	<ul style="list-style-type: none"> <li>• State Health Plan standards applied in Certificate of Need review hold FASFs to standards to minimum volume as a demonstration of need; this promotes quality and cost-effectiveness.</li> <li>• Impact on hospitals providing outpatient surgical services may be assessed during the Certificate of Need review process, and considered in review and recommended decision.</li> <li>• Most of the single OR exempted facilities remain as single specialty and provide limited real competition for hospitals and larger multi-specialty FASFs – they operate as personal operating rooms for single practitioners with low surgical volume.</li> </ul>
<b>Access</b>	<ul style="list-style-type: none"> <li>• FASFs tend to serve higher proportions of insured and privately insured patients than hospitals</li> <li>• FASFs provide more convenient access for patients than general hospitals</li> <li>• Although State Health Plan standards applied in Certificate of Need review require charity care policy and Medicaid access, compliance with these policies is difficult if not impossible to enforce.</li> </ul>	<ul style="list-style-type: none"> <li>• Competition for limited staff may add unnecessary costs to the system.</li> <li>• Because the existing program limits larger, multi-specialty FASFs from entering the market, the formation of a two-class outpatient surgery system, with proprietary FASFs dominating the private insurance and Medicare market and hospitals left with Medicaid and uninsured patients, is constrained.</li> </ul>

## Ambulatory Surgery Services: Summary of Positions in Support of Alternative Regulatory Strategies (continued)

<p><b>Cost</b></p>	<ul style="list-style-type: none"> <li>• Additional FASFs would stimulate competition and could promote cost efficiencies.</li> <li>• Larger FASFs could achieve economies of scale by providing services to more clients.</li> <li>• Reasonableness of charges in the freestanding sector is enforced by the market, not by Certificate of Need regulation.</li> </ul>	<ul style="list-style-type: none"> <li>• State Health Plan standards applied in Certificate of Need review require demonstration of “reasonable charges” by proposed new FASFs.</li> <li>• May promote unnecessary duplication of facilities (even if fewer and larger facilities are developed)</li> <li>• Large number of facilities produced by existing program already stimulates competition – deregulation would not have a large impact on increasing competitive intensity.</li> <li>• Hospitals may be forced to duplicate surgical facility capacity already in place within hospitals in order to effectively compete, on the basis of price, with development of larger, multi-specialty FASFs that could occur with deregulation.</li> </ul>
<p><b>Quality</b></p>	<ul style="list-style-type: none"> <li>• Quality/outcomes may be negatively affected by the low volumes of surgery performed by many Maryland facilities.</li> <li>• Providing sufficient quality oversight to the large number of small office-based surgical facilities in the state is already difficult, given resources constraints at OHCQ.</li> </ul>	<ul style="list-style-type: none"> <li>• State Health Plan standards applied in Certificate of Need review require new FASFs to obtain accreditation as well as licensure.</li> <li>• In order to compete for payer contracts, many non-Certificate of Need approved centers also obtain accreditation; absence of this market-entry requirement could negatively affect quality of care.</li> <li>• To the extent that the current program keeps more surgical volume in control of hospital organizations, greater levels of regulatory oversight and peer review may occur.</li> </ul>

# Interested Party status

- Benefits
  - Right to force contested case; right to present evidence and arguments; statutory right of appeal**
- Statutory minimums
  - Staff; competing applicants; others “adversely affected”; local health planning (department)**
- Comments
- Options (*examples*)
  - Third party payors**
    - Automatically “interested parties” or**
    - No special mechanism**
  - “Adversely affected”**
    - Eliminate “potential impact” test and**
    - Replace with direct, special effect plus invitation to comment?**
- Statutory changes
  - E.g., eliminate “any other person . . . adverse effect” test *or* attempt to distinguish “special” from “general” effects**

# CON Review Process

- **Completeness Review**
- **Re-docketing Rules**

## **Application Review Conference**

- The format of this conference should be a walk-through of the application and its appendices at which the staff will provide the applicant with its views on the completeness of each question or information requirement outlined in the application;
- The conference will serve to formulate the written completeness review questions with input from both staff and the applicant; and
- Because of the conference, the completeness questions, prepared by staff and given to the applicant within a reasonably short period after the ARC, will be fewer and limited to more substantive issues which could not be fully addressed at the conference or which require development of information or analyses by the applicant; and better understood by the applicant because of the applicant's participation in framing the questions at the ARC.

## **Project Status Conference**

- A Project Status Conference will be held to address those standards and review criteria which present a problem for approval of the project. Prior to this meeting, the Reviewer or staff will send a memorandum to the applicant and interested parties outlining the areas of concern so that the applicant can have appropriate persons attend the PSC.
- The PSC will be structured to allow the applicant and interested parties to ask questions about the status of the project and provide comment regarding the identified issues;
- A written summary of the PSC will be prepared for the record, along with a statement of applicant revisions to the Summary, if desired by the applicant;
- Following the PSC, the applicant will have an appropriate period of time to make changes, if desired, to the project, which cure the problems or deficiencies identified at the PSC, without the requirement for re-docketing. Each interested party will have a 10 day period in which to file comments on changes to the project.

# Capital Expenditure Review Threshold

**Table 1**  
Certificate of Need Projects and Determinations of Non-Coverage by  
Capital Expenditure: Maryland, 1995-2005 (January-May 2005)

Capital Expenditure (in millions)	All CON Projects	CON Projects-Capital Expenditure Threshold Only	All Determinations of Non-Coverage	Determinations of Non-Coverage-Hospital Pledge Projects
\$45.0 and Over	8	2	4	4
\$40.0-\$44.9	1	0	0	0
\$35.0-\$39.9	0	0	0	0
\$30.0-\$34.9	3	1	3	3
\$25.0-\$29.9	3	3	1	1
\$20.0-\$24.9	2	0	1	1
\$15.0-\$19.9	0	0	5	4
\$10.0-\$14.9	8	2	10	10
\$5.0-\$9.9	12	2	26	25
\$1.0-4.9	28	1	97	69
Under \$1.0*	138	0	53	0
<b>TOTAL</b>	<b>203</b>	<b>11</b>	<b>200</b>	<b>117</b>

Source: Maryland Health Care Commission  
(\*includes a small number of projects with no cost or costs not stated)

- Only 11 of 203 projects reviewed (5.4%) required CON review solely because they involved capital expenditures that exceeded the expenditure threshold for review.
- Conversely, 117 hospital projects involving capital expenditures exceeding the review threshold were allowed to proceed without CON review because the sponsoring hospitals “took the pledge.”
- The options for increasing the capital threshold identified in the comments include: \$5.0 million; \$7.5 million; and \$10.0 million.
  - A related issue concerns whether there should be one capital threshold for all projects, as is now the case, or whether there should be separate thresholds for acute care hospital versus nursing home/other projects.
  - Given the differences between capital projects undertaken by hospitals versus nursing homes, it could be argued that a higher threshold (e.g., \$10.0 million) should be applied to hospitals.
  - On the other hand, a single threshold have would some administrative advantages and \$7.5 million seems to have support in comments received from both hospitals and nursing homes.

# CON Task Force Meetings: Major Agenda Items

## **Meeting 1: May 26, 2005**

- Introduction of Members
- Background on Maryland CON Program
- Charge to the Task Force

## **Meeting 2: June 7, 2005**

- Public Forum on the Certificate of Need Program

## **Meeting 3: June 23, 2005**

- Specialized Health Care Services
- Hospice Services
- Health Information Technology
- Closure of Health Care Facilities

## **Meeting 4: July 14, 2005**

- Principles to Guide CON Program
- Home Health Services
- Obstetric Services

## **Meeting 5: August 11, 2005**

- Hospice Services
- Capital Expenditure Review Threshold
- Ambulatory Surgery Services
- CON Review Process Issues
  - Interested Parties
  - Completeness Review and Re-Docketing

## **Meeting 6: August 25, 2005**

- State Health Plan Issues
- Monitoring Issues
- Remaining Issues
- Review Draft of Final Task Force Report

## **Meeting 7: September 8, 2005**

- Review Draft of Final Task Force Report